The HIT Standards Committee's Implementation Workgroup Survey on the EHR Temporary Certification Program, Stage 1 Meaningful Use

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1. Please indicate what ONE group best describes you:

ATCB	Complete EHR S/V/D	Modular EHR S/V/D	EP/EH Self-certifier	EP/EH using CEHRT & attesting in 2011 or 2012	REC	Association	Other
1	5	4				5	4

Other: Minnesota e-Health Initiative, EHR services supporter (1), EHR consultant (1), person w/ unknown affiliation (1)

2. Please indicate the size of your group:

Small	Medium	Large	Not Identified
3		12	4

3. What did you gain from the Temporary Certification Program that you did not expect?

- Assisting providers and building relationships. (modular vendor)
- Consistent with expectations. (complete vendors)
- Learned that the value of the complete EHR certification was not as expected. Modular certification would have been better for the majority of clients. (complete vendor)

4. What part(s) of the Temporary Certification Program worked well and that you would not want to see changed?

- Distribution of information, access via web, blogs, FAQs. (consultant)
- Guidance and processes provided by ATCBs (and ONC). (modular & multiple complete vendors)
- Choice of testing and certification bodies. (complete vendors)
- Remote testing capabilities. (complete vendor)
- Consistency of standard NIST test procedures, although there were some variations with test scripts. (complete vendors)
- Modular certification and the ability to pursue site certification. (AHA)

5. What 3 Temporary Certification Program testing and certification process points were the confusing / most misunderstood? For these points, what could be improved and how?

- Determining whether the EHR technology installed in a particular hospital or physician office meets the certification criteria has been an unexpected challenge. (modular vendor and AHA)
- Lack of clear guidance to ATCBs has led to inconsistency. (modular vendor, AHA and CCHIT)
- CHPL reporting rules.
    - Multiple listings of vendors various certified EHR Modules as it pursues Complete EHR certification is confusing. Updating product certification line items with added functionality as they are achieved when pursuing Complete EHR certification would simplify the CHPL. Clarity is also required for modifying a certification once listed. (CCHIT)
    - Doesn't reflect industry bundling or branding terminology. Recommend clarification of the vendor applications within the EHR product that are required for each criterion, including a notation of the required sub-applications or products in the Module or Complete EHR. This will assist providers in selection. (complete vendor)
- When is site certification required? (Minn e-Health)
- FAQ 24 could have been issued sooner to prevent confusion. (complete vendor)

- Suggest (better structure) through the creation of a single resource (comprised of coordinated representatives from both ONC and CMS, for example) and a single location (one website) for guidance and for submitting questions. Additionally, we suggest including a comprehensive revision history for each FAQ. Today, it is easy to find FAQs that have been updated but often the change is only one word or a typo correction. To determine whether a substantial change was made, we must record the text of each FAQ in order to identify changes in subsequent updates. (complete vendors and AHA)
- Certification overlaps logical product boundaries (3rd party software). A modular approach may not be efficient for hospital developers who need to certify previously installed EHR technology. Hospital developers use various "best-in-breed" products and may need to certify previously installed EHR technology. In some cases, they may have two or more products that "straddle" one ONC criterion. More guidance should be given to ATCBs related to certification in this area. (large vendors and CCHIT)
- Saw situation where certification for a complete EHR was also given to EHR Modules for the same vendor. Seemed criteria from the complete EHR were 'inherited' into the Module. For example, a vendor with modular certification for an anesthesia system was approved for a CQM for emergency wait times. What do ER wait times have to do with an anesthesia system? (consultant)
- Why do ATCBs have different price points? (modular vendor)
- Version test scripts. Since test procedures can be continuously changed, it introduces unnecessary uncertainty to developers. Recommend that test procedures be versioned and that those who passed certification according to the then-current version not be required to retest. (modular and complete vendors)
- Inherited Certified Status (new releases).
    - The area of "new releases" needs to be addressed. There is little or no direction on this and issues such as updates / fixes /patches to systems need to be considered. (consultant)
    - A better formulated description of when attestation would be enough for recertification and when retesting would be required. This should take into account the possibility of situations where there are minor product changes in some program areas (which could be attested to) even if there are more significant changes in other areas (which would require testing). (*See* Natan Blank's (PeriGen) comments for details and specific example)
- Privacy and Security Testing and Certification. Application of privacy and security criteria, including exemptions, to EHR modules and for site certification needs to be clear and less burdensome. (modular vendor, complete vendors, AHA and CCHIT) (*See* Cerner's (John Travis) comments for a detailed analysis related to testing of encryption and hashing and audit logs)
- E-prescribing was initially a disaster since new fields were added and no one coordinated with Surescripts. (modular vendor)

6. What 3 meaningful use measures and their corresponding certification criteria and test procedures seemed not to be in alignment and caused confusion for you?

- CQMs (§ 170.304(j) and § 170.306(i)) and auto measure calculation (§ 170.302(n)) test scripts did not test for exceptions even though providers have that option during their attestation process. Wide interpretation of what should be in the numerator and denominator between ATCBs and vendors (provide more clarification on this topic) (*see* CCHIT specific comments in their submission). (complete vendor and CCHIT)
- CQMs. The current test scripts explicitly state that accuracy of measurement will NOT be tested, and the measures include many data elements that are not routinely collected in the EHR, as well as sophisticated concepts that may require clinical judgment to address (such as the time a physician decided to admit a patient seen in the emergency department). Fix emergency department. (AHA and complete vendor) (*See* response to certification criteria decomposition question # 9 and Cerner's (John Travis) specific CQM comments on question # 5 in its submission)

- Little correlation between steps the provider must take to conduct or review their security risk and requirements of the vendor in testing the security and privacy scripts, (§§170.302(o)-(t)). In particular, the integrity and encryption scripts were unclear as to what was expected during testing and what specific output was deemed to be acceptable. Further, the testing and output required from the EHR did not align with provider workflow or the intended use for the EHR relative to the security risk. (modular and complete vendors) (*See* Cerner's (John Travis) specific comments to question # 5 for a detailed analysis related to testing of encryption and hashing and audit logs)
- Test procedures for timely access (§ 170.304(g)) did not correspond to a typical eligible provider workflow or the process required to connect a patient to their practice to provide online access to their clinical data. Although the provider's measures require timely access within four business days to 10% of their unique patients, the testing scripts were not clear on the support that would be initiated by the provider. (complete vendor)
- § 170.304(a)/170.306(a). Objective states: Use CPOE for medication orders directly entered by any licensed healthcare professional who can enter orders into the medication record per state, local, and professional guidelines. Certification criteria require that a vendor show CPOE for medication, laboratory, and radiology/imaging orders. Why do the criteria require additional order types (confusion)? Additionally, at first, there was just too much vagueness in who could place an order and have it counted, the types of orders that could be placed and what types of workflows for entering orders could be accommodated. If the intent was to promote physician adoption, it seems at odds with that intent to allow for all manners of order transcription to be considered (*See* Cerner's (John Travis) full submission for specific questions). (2 complete vendors)
- The certification requirements for *summary of care record* and *providing patients a copy of their health information* contained a smaller set of data elements than the requirements on providers for meeting meaningful use. This has generated considerable confusion. We recommend limiting the requirements on providers to the information that can be generated by certified EHRs. (AHA)
- Smoking status and recodes. (complete vendor)
- Content of the clinical summaries CCD C32 conflict with CMS definition of their measures. (complete vendor)
- Public health surveillance. CCHIT noted removal of implementation guide, but testing and certification of products on the CHPL to the incorrect implementation guide. (complete vendor and CCHIT)
- eRx (are OTCs excluded?), exchange of clinical information, and summaries of care. (EHR service supporter)
- Confusion about providers implementing certified systems and running them in conjunction with non-certified systems. ONC FAQs have tried to address this but there are still many questions/issues. For example, if I run a certified EHR Module and a non-certified Module and both pass data into (or take data from) an interface engine and the engine also sends data to a QM database, is the QM tool considered to meet MU? Does the interface engine need to be certified (at least for P&S)? (consultant)
- Structured lab objective. Despite the guidance that the lab result should be a numeric value or a positive or negative affirmation, there still was a lot of room for interpretation of what types of lab procedures and results should be considered for numerator credit. The challenge particularly came into play for result values that could be short textual strings. (complete vendor)
- Electronic copy of the record objective. Unclear how the record could be provided, the form it needed to be provided in, whether that needed to be singular or multiple electronic files/outputs and what content really needed to be included as well as the impacts of any conditions the patient might place on the request (*See* Cerner's (John Travis) full submission for questions related to patient requests).
- Demonstrating encryption, when standard built-in features (e.g., browser, OS) are used. This is equivalent to distrusting your browser's HTTPS encryption, and the test procedure essentially

requires inserting a test tool (not part of the product) to demonstrate something that is normally "invisible." Attestation should be permitted in this case. (complete vendor)

- Performing at least one test of immunization registry and reportable labs to public health using the standards. Since states and public health agencies vary quite a bit in the standards they require or support, it is very unclear what must be done for meaningful use when the states do not support the same standards as specified by ONC. Questions submitted to the CMS questions website on this issue have gone unanswered since August 2010 until now. (complete vendor)
- Exchanging key clinical information. Means of transport of the clinical information was not specified (no standards). The impression was left with many organizations that any electronic transport would be acceptable. However, CMS recently surprised many with the ruling that use of portable electronic media is not acceptable. This should have been much clearer in the regulations and the tests, if only certain ways of exchanging (e.g., via network but not via media) were accepted. (complete vendor)

7. Are the certification criteria clear? If no, which criteria and how it can be improved?

- Yes (all and some). (consultant, modular vendor and 2 complete vendors)
- No. (complete vendor)
- No – What method of exchange is required for exchange of health information? (complete vendor)
- No – Demographics for date of death. If I can register a patient into an ancillary product such as an ICU unit, Lab, anesthesia, etc, why would you need death of death? As part of a full EHR for the front end intake process I can understand the value of that info, but why is it needed for Modular certification? (consultant)
- No – Privacy and security criteria for application (including exemptions) to EHR modules and for site certification is unclear. (modular vendor, complete vendor, AHA and CCHIT)
- No – The word "transmit" has different meanings in different places. (EHR services supporter)
- No – *See* CCHIT's specific comments on 12 certification criteria in their submission.

8. Was the level of specificity appropriate? If no, how it can be improved?

- Yes. (modular vendor and complete vendors)
- No – Does not address specialists and ancillary support activities. (consultant)

9. Should certain certification criteria be combined or decomposed differently? If yes, which criteria and why?

- No. (complete vendor)
- Yes – some of the security criteria. (modular vendor)
- Yes – Combine authentication & access controls. (consultant)
- Yes - Decompose all criteria that can impact specialty areas. (consultant)
- Ask the question: Does this apply as is at all care levels and delivery methods? For example, vital signs – growth charts. Client is considering adding growth charts to its product due to competitive reasons because getting certified on the 'vital signs' certification criterion is important, yet their customers (specialty/ancillary providers) will have no real need for that capability. (consultant)
- Yes – Audit test procedure should be decomposed into two procedures to allow for security audit log products to be able to be tested independently. (complete vendor)
- Yes – All of the public health reporting objectives could be decomposed to allow for public health reporting applications to be able to clearly standalone and be certified as EHR modules. The criteria is defined to focus on the ability of the EHR to submit public health reporting data in a conformant manner to a defined specification, but the test procedure lays out a presumption that manual data entry in a source EHR need be the starting point for testing the criteria. The test procedure should allow for a starting point that the system is able to acquire the inbound data from a source system by showing how such inbound files are obtained. (complete vendor)
- Yes – Calculate and submit CQMs and automated measure calculation. These criteria require that a vendor report on all measures (CQMs and objectives), but some vendors test against only a

subset of objectives, while others are specialty systems that may be able to report only on specific quality measures. Suggest that vendors be allowed to test against a subset of measures for reporting. (complete vendor) / CQMs for emergency departments. (complete vendor and AHA)

10. Should certain certification criteria be scoped differently? If yes, which criteria and why?

- No. (modular vendor and complete vendor)
- Yes – More detail should be added to the description of the criteria. (modular vendor)
- Yes – Auditing, encryption and integrity, public health reporting (lab, syndrome and immunization), CQMs. *See* comments under questions 5, 6 and 9. (complete vendors)
- Yes. (CCHIT)
    - § 170.302(p) Emergency Access—match to Final Rule and test both "Break the Glass" for a patient medical emergency and also for situations like natural disaster emergencies.
    - § 170.302(a) Drug-drug, drug-allergy interaction checks—the appropriateness of disabling drug-allergy interactions should be reviewed and removed from the scope of this criterion for patient safety reasons.
    - § 170.302(j) Medication Reconciliation—the current criterion and test method do not test true medication reconciliation.

11. Please comment on the balance of process-oriented vs. outcome-oriented certification criteria.

- Criteria are very heavy towards outcomes at this point. More will need to be done on interdisciplinary criteria before you see real clinical process improvement. (consultant)
- Criteria are process-oriented. EPs/EHs should be measured on outcome-oriented criteria. HITECH auditing process would be the appropriate place to measure outcome-oriented criteria. Clinical workflow should not be "prescriptively" specified in the certification criteria. Examples are OK, but EHRs should not be required to follow them exactly. (complete vendor)
- Results and outcomes should more closely align with EPs/EHs MU objectives and use of certified EHRs. An example of an overly process-oriented demonstration is the criteria associated with the smoking status (§ 170.302(g)). Over nine tests were required for each code, when a lesser number would have proved the function. Another example is the meaningful use objective to record and chart vital signs, calculated body mass index and plot and display growth (§ 170.302(f)). The testing process did not reflect the workflow that would be used by the provider to accomplish the objective and the purpose of the testing process was unclear. (complete vendor)
- No imbalance noticed. (complete vendor)
- Confusing question. (multiple commenters)

12. Do you have any suggestions for improving the ONC-approved test procedures for EHR certification?

- § 170.304(a) - separate the testing of a radiology and laboratory order from a medication order type. In many EHRs, those applications are sold and installed separately. (complete vendor)
- Allergy –why we would set severities? (modular vendor)
- State expected results. If it is up to the vendor for display, then say so. State why things are needed a certain way. Interpretation was difficult. (modular vendor)
- Examples of valid testing approaches within the context of the test procedures would serve to help vendors prepare. (complete vendors)
- Although an optional test, the accounting of disclosure (§ 170.302(w)) description/test was very brief and does not provide enough information for the vendor to assess its capability. Lack of clarity may have contributed to why only a few EHRs tested against this script. (complete vendor)
- Don't use obsolete drugs (option of drugs in general). (modular and complete vendors)
- More specifics and directions for integrity and encryption (apply to CCR & CCD?). (consultant)
- There should be a more formal process for release of test procedures, collection of feedback, and publication of final test procedures, with scheduled dates associated with each step. Clinical and vendor review will also help catch basic mistakes in the procedures related to content, such as discontinued medications that were included in the scripts. As to process, it could be handled via

an open web-based process and/or e-mail box to submit questions, suggestions for improvements, and clarifications. (complete vendors)

- Recommend that test scripts and changes to test scripts be announced (at least 60 days) in advance. (complete vendors)
- Since test procedures can be continuously changed, it introduces unnecessary uncertainty to developers. Recommend that test procedures be versioned, and that those who passed certification according to the then-current version not be required to retest. (modular and complete vendors)
- Formatting the NIST test procedures in the form of a script would be useful. (complete vendor)
- *See* CCHIT's specific comments on 12 certification criteria in their submission.

13. Would it be beneficial if more choreographed/combined test procedures were developed that permitted an EHR developer to satisfy multiple certification criteria at once?

- No – may hamper modular systems. (consultant)
- No. (complete vendors)
- Yes. (modular and complete vendors)
- Yes – There are four test steps that are entirely repeated between access control and authentication. Another example is for testing encryption of data in transit and general encryption. We are aware that ATCBs have allowed vendors to test both of those procedures with the same example of encryption. Either combine the two test procedures or require different encryption capabilities to be tested between them. (complete vendor)
- Yes – *See* CCHIT's response to question # 9 in their submission.

14. In what ways can the test procedures be combined to facilitate the testing of certification criteria within the context of clinical workflow?

- *See* CCHIT's response to question # 9 in their submission.
- Recommend combining medication ordering, electronic prescription and drug-formulary checking scripts (§§ 170.304(a), 170.304(b) and 170.302(b)). (complete vendor)
- There is redundancy with the exchange scripts (§ 170.306(d) with § 170.306(f) and § 170.304(i) and § 170.304(f)). Recommend they be combined or tested together. (complete vendor)
- Recommend that the testing processes for security scripts that cover the different types of access and controls (§ 170.302 (o), (p), (q) and (t)) and the security scripts that cover integrity and encryption (§ 170.302(s), (u), and (v)) be combined. (complete vendor)
- Adding clinical context to the actual test procedures may go a long way towards facilitating this goal. Our ATCB produced test scripts that incorporated patients and office visits into the scripts, which helped give us a better idea of the clinical workflows we would demonstrate during the test and clarified what we needed to do for certification preparation. (complete vendor)
- Consider organizing the test procedures in the order they would be performed during a patient's typical hospital or clinic stay. (complete vendor)
- Test procedures that align to a clinical workflow could be combined into a story of sorts that provides for a linear flow to allow for multiple test procedures to be tested in one overall flow. For EPs, CPOE, CDS, drug based alerting and eRx could be tested together. For hospitals, CPOE, CDS, drug-formulary checking and drug based alerting could be tested as a continuous flow. Other combinations also seem possible centered on discharge or departure from a physician office including medication reconciliation, discharge instructions or patient education and providing an electronic copy of the record. (complete vendor)

15. Please provide specific instances where the ONC-approved test method can be improved to reduce ambiguity, inconsistency with criteria, and addition of implicit requirements beyond the certification criteria.

- NIST tools that are used prior to and during testing to validate many of the scripts output are incomplete. Therefore, the ATCB proctors were required to conduct a visual inspection of some of the records and XML before certifying the vendor's EHR. Recommend that the ATCBs

develop and deploy additional validation tools to eliminate the guesswork for some of the record layouts and data elements. (complete vendor)

- Test method for § 170.304(h) requires that vendors provide clinical summaries electronically. The criterion requires that clinical summaries are provided to patients via the EHR, but only states "if the clinical summary is provided electronically…" This electronic requirement seems to go above and beyond the criterion itself. (complete vendor)
- Data necessary for generating the CCD - it is difficult to backdate data. (complete vendor)
- Public health surveillance requirements were very vague. (complete vendor)
- Patient list by conditions in the original test script from NIST. (complete vendor)
- *See* CCHIT's response to this question in their submission (comments on 18 + criteria).

16. How would you rate your certification experience on a scale from 1 (difficult) to 6 (easy)?

- 3. (consultant, modular vendor and 2 complete vendors)
- 2. (complete vendor and AHA on behalf of its members)

17. Other Comments or Suggestions

- Possession
    - Possession of entire certified Complete EHR leads to redundant licensing for customers/providers. (complete vendor and AHA)
    - Financial burden on vendors to certify multiple combinations. (AHA)
    - Financial burden on providers. (Minn e-Health)
    - Bias towards Complete EHR vendors or single-vendor solutions. (2 modular vendors, consultant, and AHA)
    - "Best-in-breed" EHR Module developers have a hard time convincing EPs/EHs to buy duplicative products. (2 modular vendors and consultant)
    - Recommend ONC requiring vendors obtain modular certification of their products. (modular vendor)
    - ONC should educate providers on a modular purchasing approach (and/or) not require them to purchase the entire Complete EHR. (modular vendor & Minn e-Health)
    - *Derivation.* Allow vendors to sell and providers to purchases "parts" of a certified Complete EHR. (complete vendors and AHA)
- CEHRT - Expected that hospitals (and EPs) must have CEHRT only for whichever modules they were going to use for MU. (complete vendors and AHA)
- Suggest more guidance and education to meaningful users to make it clear where there are difference in the certification criteria and the MU incentive requirements, such as the privacy and security certification criteria and the requirement for a security audit. (complete vendor)
- Outside of the requirement for the CCR/CCD, very little in the MU criteria that addresses clinical workflow in a hospital setting. Interdisciplinary (and interdepartmental) application of checklists would greatly reduce care errors and costs. (consultant)
- Vendors have too much flexibility to interpret the rules during their software design. Example given was NextGen's decision on how to define "unique patient." This misunderstanding was addressed by ONC/CMS. (EHR services supporter)
- Provide computer-retrievable knowledge at the point of care. (person unaffiliated)
- AHA (additional) comments (*See* AHA submission):
    - Provided excerpt from letter and slide deck that was also provided to the Secretary, CMS and ONC.
    - The slide deck and letter to the Secretary were a collaborative effort with the Federation of American Hospitals, the College of Health Information Management Executives, the Association of Medical Directors of Information Systems, HIMSS, and the HIMMS Electronic Health Record Association.
    - As noted by AHA, excerpted questions have been answered by ONC and CMS FAQs.
    - Make publically available all CMS EHR certification IDs created on the CHPL.

    - Allow providers to modify or substitute technology components incorporated into a criterion as long as the original EHR was certified.
- CPCA comments:
    - Dentists are EPs, yet there are no oral health measures in meaningful use or standards for certified electronic dental records (EDRs). EHRs were not created for a dental practice.
    - ONC should develop a certification standard, in cooperation with the American Dental Association, specifically for EDRs that will make the certification program more accessible to oral health professionals.
- AAP comments:
    - "…some risk that purchasers who acquire systems under that Temporary status, will not get a fully-certified product, since a vendor can elect to discontinue prior to permanent certification."
    - ONC should work with AAP on end-products that pediatricians need.
    - ONC = coordinator of standards/ATCBs = "measure adherence to certification."
- AAO comments:
    - Criteria do not adequately address interoperability and information exchange capabilities for image-based specialties such as ophthalmology, radiology, and cardiology.
    - Few vendors comply with data representation and exchange standards. Creates a significant obstacle to widespread adoption by the specialty, including difficulties involving manual data re-entry into patient records, image data residing in multiple locations, the need to scan results into EHR systems, and the need to develop proprietary device interfaces. Concerned that this increases the risk of errors when such electronic data are entered incorrectly or not available at the point of care.
    - Recommend § 170.304(i) include diagnostic images in the types of information that a certified EHR is required to electronically receive, display and transmit. Also recommend adoption of DICOM.
- CAP comments:
    - EHRs as defined by ONC rules are not used in pathology. Pathologists and their laboratories have long relied on laboratory information systems (LISs).
    - § 170.302(g) basically only requires that CLIA requirements for laboratory reports are met. Recommend that criteria include requirements that laboratory result display and handling in an EHR is appropriate and flexible enough to account for the complexity of laboratory result display to support clinical interpretation and patient care. Examples of testing that may require unique considerations in data display include: Microbiology, Blood bank/transfusion medicine, Molecular pathology and genetic testing, etc. Examples of laboratory reports that may be prone to suboptimal handling in EHR systems include: reference ranges (normal ranges), reflex test orders and results, etc. (*See* CAP submission for entire lists and further detail)
    - CPOE will meet goals for laboratory test ordering only if; (1) capabilities that are necessary to meet requirements of all of the nuances of laboratory test ordering exist in the CPOE system/module; and (2) organizations and providers using CPOE configure the CPOE system in a way that ensures proper ordering of laboratory tests. (*See* CAP submission for further details)
- Minnesota e-Health Initiative (additional) comments:
    - Recommend integration and interoperability testing of EHR Modules and components of Complete EHRs as part of the certification process.
    - Establish pricing mechanisms for certification.
    - Certify other HIT, including PHRs, networks for health exchange, etc.
    - Assumes that EHR technology will be certified by MU Stages.